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DATE MAILED: 01/12/2005

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/724,527	11/28/2003	Cedric Francois	LOU02-016-US	8907
43320 7	590 01/12/2005		EXAMINER	
EVAN LAW GROUP LLC			CHANDRA, GYAN	
566 WEST ADAMS, SUITE 350 CHICAGO, IL 60661		ART UNIT	PAPER NUMBER	
CHICAGO, II	2 00001		1646	

Please find below and/or attached an Office communication concerning this application or proceeding.

Application No. Applicant(s)					
Office Action Summary  10/724,527 FRANCOIS, CEDRIC  Examiner Art Unit					
Examiner Art Unit					
Gyan Chandra 1646					
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply					
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).	on.				
Status					
1) Responsive to communication(s) filed on 14 December 2004.					
2a) ☐ This action is <b>FINAL</b> . 2b) ☒ This action is non-final.					
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits	is				
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.					
Disposition of Claims					
4)⊠ Claim(s) <u>1-39</u> is/are pending in the application.					
4a) Of the above claim(s) is/are withdrawn from consideration.					
5) Claim(s) is/are allowed.					
6) Claim(s) is/are rejected.					
7) Claim(s) is/are objected to.					
8) Claim(s) 1-39 are subject to restriction and/or election requirement.					
Application Papers					
9)☐ The specification is objected to by the Examiner.					
0) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.					
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).					
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121	(d).				
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.					
Priority under 35 U.S.C. § 119					
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).					
a) ☐ All b) ☐ Some * c) ☐ None of:					
<ol> <li>Certified copies of the priority documents have been received.</li> </ol>					
2. Certified copies of the priority documents have been received in Application No					
3. Copies of the certified copies of the priority documents have been received in this National Stage					
application from the International Bureau (PCT Rule 17.2(a)).					
* See the attached detailed Office action for a list of the certified copies not received.					
Attachment(s)					
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 4) Interview Summary (PTO-413) Paper No(s)/Mail Date					
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date  5) Notice of Informal Patent Application (PTO-152) Control of Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Control of Information D					

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## **DETAILED ACTION**

## Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1-9, and 19, drawn to a method of treating a transplant comprising a T cell apoptosis inducing agent and a phospholipid.

Group 2, claim(s) 10 -18, drawn to a method of treating a transplant comprising administering a vesicle comprising a phospholipids, at least one member selected from the group consisting of another polar lipid, a raft former and a fusion protein, and a lipid.

Group 3, claim(s) 20-23, drawn to a vesicle comprising a phospholipid and a T cell apoptosis-inducing molecule.

Group 4, claim(s) 24-31, drawn to a vesicle comprising a phospholipid, a T cell apoptosis-inducing molecule and a polar lipid.

Group 5, claim(s) 32, drawn to a transplant contacted with a vesicle.

Group 6, claim(s) 33-36, drawn to a method of transplanting a transplant.

Group 7, claim(s) 37-39, drawn to a method of treating a transplant comprising administering a T cell-apoptosis-inducing molecule, and a vesicle comprising a means for binding the T-cell-apoptosis-inducing molecule and a phospholipid where the vesicle has a fusion rate of 20 vesicle fusions/second.

The inventions listed as Groups 1-7 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

I. Group 1, recites the special technical feature of treating a transplant comprising a T cell apoptosis inducing agent and a phospholipid, which is not required by other methods of Groups 2, and 6-7.

II. Group 2, recites the special technical feature treating a transplant comprising administering a vesicle comprising a phospholipids, at least one member selected from the group consisting of another polar lipid, a raft former and a fusion protein, and a lipid, which is not required by other methods of Groups 1, and 6-7.

- III. Group 3, recites the special technical feature of a vesicle comprising a phospholipid and a T cell apoptosis-inducing molecule, which is not required by other products of Groups 4, and 5.
- IV. Group 4, recites the special technical feature of a vesicle comprising a phospholipid, a T cell apoptosis-inducing molecule and a polar lipid, which is not required by other products of Groups 3, and 5.
- V. Group 5 recites the special technical feature of a transplant contacted with a vesicle, which is not required by other products of Groups 3-4.
- VI. Group 6, recites the special technical feature of transplanting a transplant, which is not required by other methods of Groups 1-2 and 7.
- VII. Group 7, recites the special technical feature of treating a transplant comprising administering a T cell-apoptosis-inducing molecule, and a vesicle comprising a means for binding the T-cell-apoptosis-inducing molecule and a phospholipid where the vesicle has a fusion rate of 20 vesicle fusions/second, which is not required by other methods of Groups 1-2 and 6.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

- A. A phospholipid selected from:
- i) 1,2-dioleoyl-sn-glycero-3-phosphocholine
- ii) 1-palmitoyl-2-docosahexaenoyl-sn-glycero-3-phosphocholine

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

Claims 24.

The following claim(s) are generic: claim 24.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

The special technical feature of (i) is 1,2-dioleoyl-sn-glycero-3-phosphocholine. This special feature is not shared by any other species.

The special technical feature of (ii) is 1-palmitoyl-2-docosahexaenoyl-sn-glycero-3-phosphocholine. This special feature is not shared by any other species.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

- B. A polar lipid is selected from formula:
- iii) formula XVII
- iv) formula XVIII
- v) formula XIX
- vi) formula XX
- vii) formula XXI
- viii) formula XXII
- ix) formula XXIII
- x) formula XXV
- xi) formula XXVI

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

Claims 24.

The following claim(s) are generic: claim 24.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

The special technical feature of (iii) is formula XVII. This special feature is not shared by any other species.

The special technical feature of (iv) is formula XVIII. This special feature is not shared by any other species.

The special technical feature of (v) is formula XIX. This special feature is not shared by any other species.

The special technical feature of (vi) is formula XX. This special feature is not shared by any other species.

The special technical feature of (vii) is formula XXI. This special feature is not shared by any other species.

The special technical feature of (viii) is formula XXII. This special feature is not shared by any other species.

The special technical feature of (ix) is formula XXIII. This special feature is not shared by any other species.

The special technical feature of (x) is formula XXV. This special feature is not shared by any other species.

The special technical feature of (xi) is formula XXVI. This special feature is not shared by any other species.

If Applicant selects group 4, one species from the phospholipid group, and one species from the polar lipid group must also be chosen to be considered fully responsive.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply

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where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gyan Chandra whose telephone number is (571) 272-2922. The examiner can normally be reached on 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gyan Chandra AU 1646 03 January 2005

JANET ANDRES
PRIMARY EXAMINER